ST 08-0071-GIL 04/29/2008 MEDICAL APPLIANCES

This letter provides a reference to the Department's rules regarding the State tax rate applicable to food, drugs, medicines and medical appliances. See 86 Ill. Adm. Code 130.310. (This is a GIL.)

April 29, 2008

Dear Xxxxx:

This letter is in response to your letter dated September 20, 2007, in which you request information. The Department issues two types of letter rulings. Private Letter Rulings ("PLRs") are issued by the Department in response to specific taxpayer inquiries concerning the application of a tax statute or rule to a particular fact situation. A PLR is binding on the Department, but only as to the taxpayer who is the subject of the request for ruling and only to the extent the facts recited in the PLR are correct and complete. Persons seeking PLRs must comply with the procedures for PLRs found in the Department's regulations at 2 Ill. Adm. Code 1200.110. The purpose of a General Information Letter ("GIL") is to direct taxpayers to Department regulations or other sources of information regarding the topic about which they have inquired. A GIL is not a statement of Department policy and is not binding on the Department. See 2 Ill. Adm. Code 1200.120. You may access our website at www.tax.illinois.gov to review regulations, letter rulings and other types of information relevant to your inquiry.

The nature of your inquiry and the information you have provided require that we respond with a GIL. In your letter you have stated and made inquiry as follows:

> I am requesting a ruling for ABC's products to determine if our products are subject to sales tax in your state. ABC is a medical device company focused on bringing solutions to interventional cardiologists and interventional radiologists. The products are as follows:
>
> **D-Stat Flowable** hemostat is a flowable hemostat composed of thrombin, collagen, and diluent. Both the thrombin and collagen are packaged dry and must be reconstituted with the diluent prior to use. Once reconstituted, D-Stat Flowable is delivered topically from the syringe to the target bleeding site using the provided applicator tips. It is indicated for the control surface bleeding from vascular access sites and percutaneous catheters or tubes. It is also used as an adjunct treatment in sealing residual oozing of tissue tracts of femoral access sites that have been previously closed by suture/collagen-based hemostatic devices. Hemostasis of the bleeding site is achieved through the physiological coagulation-inducing properties of D-Stat. This is a disposable, single use product. Federal law restricts this device to sale by or on the order of a physician. The D-Stat Flowable procedure should be performed by physicians or physician-directed allied health care professionals with adequate training in the use of the device. Please see the D-Stat Flowable *Instructions for Use* for a complete listing of the indications, contraindications, warnings and precautions.

D-Stat Dry Hemostatic Bandage is a dry hemostatic gauze pad with an adhesive bandage that quickly clots blood. It is intended to be used in a broad variety of topical bleeding situations to stop the bleeding quickly in a simple, no-mixing, open-and-apply configuration. D-Stat Dry consists of two components – a gauze pad that consists of primarily thrombin and D-Stat lyophilized (freeze-dried) into the pad, and a custom-sized adhesive bandage to go over the pad. This is a disposable, single use product. Federal law restricts this device to sale by or on the order of a physician. Please see the D-Stat Dry *Instructions for Use* for a complete listing of the indications, contradictions, warnings and precautions.

D-Stat Radial is a hemostatic band designed to be used after catheterizations using the radial artery in the wrist and deliver the power of D-Stat to assist the hemostasis process. D-Stat Radial consists of a gauze pad that has thrombin lyophilized (freeze-dried) into the gauze, just like our D-Stat Dry. The gauze is attached to a release tab which is attached to a compressible translucent pad. Pressure is exerted over the puncture site through a collar and retention strap that holds the pad in place. Two foam pads are attached to improve patient comfort. This is a disposable, single use product. Federal law restricts this device to sale by or on the order of a physician. The D-Stat Radial procedure should be performed by physicians or physician-directed allied health care professionals with adequate training in the use of the device. Please see the D-Stat Radial *Instructions for Use* for a complete listing of the indications, contraindications, warnings and precautions.

D-Stat Clamp Accessory is a hemostatic band designed to be used with standard clamp devices to deliver the power of the D-Stat to assist the hemostasis process. The D-Stat Clamp consists of a gauze pad, just like our D-Stat Dry. The gauze is attached to compressible foam for exerting pressure over the puncture, and a plastic attachment base holds the pad and the foam in place. This is a disposable, single use product. Federal law restricts this device to sale or [sic] by or on the order of a physician. The D-Stat Clamp procedure should be performed by physicians or physician-directed allied health care professionals with adequate training in the use of the device. Please see the D-Stat Clamp *Instructions for Use* for a complete listing of the indications, contraindications, warnings and precautions.

ThrombiGel is a thrombin/gelatin foam hemostat that is applied topically and is indicated as a trauma dressing for temporary control of moderate to severely bleeding wounds and for the control of surface bleeding from vascular access sites and percutaneous catheters and tubes. This is a single use product. Federal law restricts this device to sale by or on the order of a physician. Please see ThrombiGel *Instructions for Use* for a complete listing of the indications, contraindications, warnings and precautions.

Pronto Extraction Catheter is a simple extraction catheter system for the removal of soft thrombus from the arterial system. The Pronto consists of a flexible, soft tipped catheter that can be placed over a guidewire and through a 6F guide catheter to the location of the thrombus, together with a syringe that can be used to manually extract the thrombus out of the vessel. The syringe has a ‘locking’ mechanism that allows the operator to lock a vacuum into the syringe before it is deployed, with the vacuum extraction automatically starting when the stopcock is turned open. This is a disposable, single use product. Federal law restricts this device to sale by or on the order of a physician. The Pronto Extraction Catheter procedure should be performed by physicians with adequate training in the use of the device. Please see the Pronto

Instructions for Use for a complete listing of the indications, contraindications, warnings and precautions.

Pronto .035" Extraction Catheter (PRONTO .035") is a dual lumen, over-the-wire (OTW) catheter with related accessories. The catheter is designed to be delivered through a 10F or larger introducer sheath over a 0.035" guidewire. The larger lumen allows for the removal of the thrombus by use of the included syringe through the extension line and stopcock. The catheter has a rounded distal tip with a protected extraction lumen to facilitate advancement of the catheter into the blood vessel and to maximize extraction of the thrombus through the extraction lumen. The catheter has a radiopaque marker band located approximately 4mm from the distal tip. The proximal end of the catheter incorporates a hemostatic Y-junction that allows for the attachment of the catheter to the included extension line, stopcock and syringe and can be tightened onto the guidewire to prevent blood leakage. This is supplied sterile and is for single use only. The PRONTO™ .035" Extraction Catheter procedure should be performed by physicians with adequate training in the use of the device. Federal law restricts this device to sale by or on the order of a physician. Please see the PRONTO™ .035" Extraction Catheter *Instructions for Use* for a complete listing of the indications, contraindications, warnings and precautions.

Pronto Short extraction catheter is a dual lumen, over-the-wire (OTW) catheter with related accessories. The catheter is designed to be delivered through a 6F or larger introducer sheath over the included 0.018" (0.45mm) guidewire. The larger lumen allows for the removal of thrombus by use of the included syringes through the extension line and 3-way stopcock. The catheter has a rounded distal tip with a protected, sloped opening of the extraction lumen to facilitate advancement of the catheter into the blood vessel or vascular graft and maximize extraction of thrombus through the extraction lumen. The catheter has a radiopaque marker band located approximately 3mm from the distal tip. The proximal end of the catheter incorporates a hemostatic Y-junction that allows for the attachment of the catheter to the included extension line, 3-way stopcock and syringes; and can be tightened down on the guidewire to prevent blood leakage. A 74 micron filter basket is included for assistance in filtering the blood removed during the procedure for laboratory analysis of any thrombus. It is a sterilized, single use product. The PRONTO-Short extraction catheter procedure should be performed by physicians with adequate training in the use of the device. Federal law restricts this device to sale by or on the order of a physician. Please see the PRONTO™-Short Extraction catheter *Instructions for Use* for a complete listing of the indications, contraindications, warnings and precautions.

Pronto V3 extraction catheter (PRONTO) is a dual lumen rapid exchange catheter with related accessories. The smaller wire lumen of the catheter is able to accommodate guidewires that are $\leq$ 0.014"/ 0.36mm in diameter. The larger extraction lumen allows for the removal of thrombus by use of the included syringe through the extension line and stopcock. The catheter has a rounded distal tip with a protected, sloped opening of the extraction lumen to facilitate advancement of the catheter into the blood vessel and maximize extraction of thrombus through the extraction lumen. The catheter has a proximal stiff region and a distal flexible region with a lubricious hydrophilic coating. The catheter has a radiopaque marker band located approximately 2mm from the distal tip. The shaft of the PRONTO catheter has two (2) non-radiopaque positioning marks located approximately 95cm and 105cm proximal of the distal tip. The proximal end of the catheter incorporates a standard luer adapter to facilitate the attachment of catheter to the included extension line, stopcock and syringes. A filter basket is included for

assistance in filtering the blood removed during the procedure for laboratory analysis of any thrombosis. It is a sterilized, single use product. The PRONTO V3 extraction catheter procedure should be performed by physicians with adequate training in the use of the device. Federal law restricts this device to sale by or on the order of a physician. Please see the PRONTO™ V3 Extraction Catheter *Instructions for Use* for a complete listing of the indications, contraindications, warnings and precautions.

Pronto LP extraction catheter is a dual lumen, rapid exchange catheter with related accessories. The smaller wire lumen of the catheter is able to accommodate guidewires that are <0.014"/0.36mm in diameter. The larger extraction lumen comes pre-loaded with a stylet that resists kinking during delivery but is removed to allow for the removal of thrombus by aspiration. The Pronto LP catheter is indicated for the removal of fresh, soft emboli and thrombi from vessels in the coronary and peripheral system. This is supplied sterile and is for single use only. The PRONTO™ LP Extraction Catheter procedure should be performed by physicians with adequate training in the use of the device. Federal law restricts this device to sale by or on the order of a physician. Please see the PRONTO™ LP Extraction Catheter *Instructions for Use* for a complete listing of the indications, contraindications, warnings and precautions.

Langston Dual Lumen Pigtail Catheter is indicated for delivery of contrast medium in angiographic studies and for simultaneous pressure measurement from two sites. It accurately measures the pressure gradient across the aortic valve. This type of pressure measurement is useful in determining transvascular, intravascular and intraventricular pressure gradients. This is a disposable, single use product. Federal law restricts this device to sale by or on the order of a physician. The Langston dual lumen pigtail catheter should be used by physicians thoroughly trained in percutaneous, intravascular techniques and procedures. Please see the Langston Dual Lumen Pigtail Catheter *Instructions for Use* for a complete listing of the indications, contraindications, warnings and precautions.

Twin-Pass (Twin-Pass .023) catheter is intended to be used in conjunction with steerable guidewires in order to access discrete regions of the coronary and peripheral arterial vasculature, to facilitate placement and exchange of guidewires and other intervention devices, for use during two guidewire procedures and to subselectively infuse/deliver diagnostic or therapeutic agents. This is a disposable, single use product. Federal law restricts this device to sale by or on the order of a physician. The TWIN-PASS catheter deployment procedure should be performed by physicians thoroughly trained in percutaneous, intravascular techniques and procedures. Please see the TWIN-PASS Dual Access Catheter *Instructions for Use* for a complete listing of the indications, contraindications, warnings and precautions.

Skyway support catheters are intended to be used in conjunction with steerable guidewires in order to access discreet regions of the arterial and or coronary vasculature. It may be used to facilitate placement and exchange of guidewires and other intervention devices. The SKYWAY OTW also may be used to subselectively infuse/deliver therapeutic agents. This is a disposable, single use product. Federal law restricts this device to sale by or on the order of a physician. The SKYWAY catheter deployment procedure should be performed by physicians thoroughly trained in percutaneous, intravascular techniques and procedures. Please see the SKYWAY OTW Support Catheter *Instructions for Use* for a complete listing of indications, contraindications, warnings and precautions.

Duett sealing device is indicated for sealing femoral arterial puncture sites and reducing time to hemostasis and ambulation in patients who have undergone diagnostic or interventional endovascular procedures using a 5F - 9F introducer sheath with an overall length not exceeding 15.2 cm. It is a two-component system that consists of a balloon catheter and a biological flowable procoagulant. The procoagulant is a mixture of thrombin, collagen and diluent. While the balloon catheter temporarily seals the arteriotomy, the procoagulant is delivered to the entire arterial access site. The procoagulant initiates the body's own clotting mechanisms to form the complete seal of both the arteriotomy and tissue tract. The Duett is supplied sterile as a disposable, single use product. Federal law restricts this device to sale by or on the order of a physician. The Duett deployment procedure should be performed by physicians or physician-directed allied health care professionals with adequate training in the use of the device. Please see the Duett sealing device *Instructions for Use* for a complete listing of the indications, contraindications, warnings and precautions.

Max-Support Abdominal Retraction Belt is a tape free method of lifting the abdomen of obese patients thereby allowing access to the femoral crease. It consists of a 'belt' with 2 fabric 'cradles' for lifting tissue away from both the left and right groins. Max-Support Abdominal Retraction Belt is supplied sterile as a single use, disposable product. Federal law restricts this device to sale by or on the order of an allied health care professional. Please see the Max-Support Abdominal Retraction Belt *Instructions for Use* for more information.

Auto-Fill Syringe is indicated for introduction of dilute lidocaine solutions into the subcutaneous tissue for the purposes of tumescent local anesthesia. The syringe delivers multiple doses of fluid without the need to manually reload the syringe. This product includes an extension tubing mechanism to conveniently refill a 10cc syringe from an IV bag eliminating the need for multiple reconnections to the solution container. Auto-Fill Syringe also contains a 10cc polycarbonate control syringe, IV tubing with spike, dual check valve, and roller clamp. Lidocaine is NOT provided. Auto-Fill Syringe is supplied sterile as a disposable, single-use product. Federal law restricts this device to sale by or on the order of a physician. Please see the Auto-Fill *Instructions for Use* for a complete listing of the indications, contraindications, warnings and precautions.

Vaclok Syringe maintains negative pressure through a 'twist and lock' motion, eliminating the tedious task of holding the plunger for extraction. The 'locking' mechanism allows the operator to lock a vacuum into the syringe before it is deployed, with the vacuum extraction automatically starting when the stopcock is turned open. Vaclok Syringe is supplied sterile as a disposable, single use product. Federal law restricts this device to sale by or on the order of a physician.

Micro-Inducer Kits are intended to introduce up to a 0.038 inch guidewire or catheter into the vascular system using a 21 gauge needle stick. They are available with regular or 'stiffen' version of dilators and available with stainless steel or nitinol guidewires and stainless or platinum coil tips. Micro-Inducers are supplied sterile as a disposable, single use product, Federal law restricts this device to sale by or on the order of a physician.

Guidewire is a long, flexible, fine spring used to introduce and position an intravascular catheter. Guidewires are supplied sterile as a disposable, single use product. Federal law restricts this device to sale by or on the order of a physician.

Vari-Lase Console is indicated for the treatment of varicose veins and varicosities associated with the superficial reflux of the Great Saphenous Vein and for treatment of incompetence and reflux of superficial veins in the lower extremity. It is a solid state diode laser console for use with the Vari-Lase Endovenous Laser Procedure Kit in endovenous laser therapy. The console operates at 810nm and goes up to 30 watts. The Vari-Lase Console is intended for repeated use. Federal law restricts this device to sale by or on the order of a physician. Please see the *Instructions for Use* for a complete listing of the indications, contraindications, warnings and precautions.

Vari-Lase Endovenous Laser Procedure Kit is indicated for the treatment of varicose veins and varicosities associated with the superficial reflux of the Great Saphenous Vein and for treatment of incompetence and reflux of superficial veins in the lower extremity. It is a kit of disposable components used in conjunction with a solid state diode laser console operating at wavelengths of 810nm, 940nm or 980nm and a maximum power of 15W. Each package contains one or more of the following components: core laser fiber (3.5 m, with or without markings), fiber lock, introducer sheath or catheter, 0.035"/0.89mm guidewire, 19 gauge percutaneous entry needle, and micro-introducer kit or micro-introducer components (consisting of a 21 gauge percutaneous entry needle, micro-access introducer with dilator, 0.018"/0.45mm guidewire). The laser fiber is contained within a dispensing coil. The catheter contains a radiopaque marker located at the distal tip. The introducer sheaths are available with or without distance indicator markings to assist in the placement and location of the laser fiber. The Vari-Lase Procedure Kit is supplied sterile as a disposable, single use product. Federal law restricts this device to sale by or on the order of a physician. Please see the Vari-Lase Endovenous Laser Procedure it *Instructions for Use* for a complete listing of the indications, contraindications, warnings and precautions.

Vari-Lase Procedure Pack is a complete sterile pack of accessories designed for endovenous laser procedures. The pack includes syringes, needles, scalpel, prep table cover, gowns drapes, gauze pads, O.R. towels, ultrasound probe cover, self-adherent wrap, lidocaine, ultrasound gel, iodine prep solutions, sponge, utility bowl, IV access tubing, skin marking pen and flexible ruler. This is supplied sterile as a disposable, single use product. Federal law restricts this device to sale by or on the order of a physician. The Vari-Lase procedure should be performed by physicians with adequate training in the use of the device.

Vari-Lase Bright Tip endovenous laser procedure kit and components are disposable items used in conjunction with a solid state diode laser console operating at wavelengths of 810nm, 940nm or 980 nm and a maximum power of 15W. Each package contains one or more of the following components: core laser fiber (3.5 m, with or without markings, with ceramic distal tip), fiber lock, introducer sheath with or without marks (multiple lengths), Vari-Lase Flex™ catheter with radiopaque marker at distal tip (multiple lengths), 0.035"/0.89mm or 0.018"/0.45mm guidewires, 19 gauge or 21 gauge percutaneous entry needle, and micro-introducer kit or micro-introducer components (consisting of a 21 gauge percutaneous entry needle, micro-access introducer with dilator, 0.018"/0.45mm guidewire). The laser fiber is contained within a dispensing coil. The Vari-Lase Procedure Kit is supplied sterile as a disposable, single use product. Federal law restricts this device to sale by or on the order of a physician. Please see the Vari-Lase Endovenous Laser Procedure Kit *Instructions for Use* for a complete listing of the indications, contraindications, warnings and precautions.

Laser Protect Eyewear is used when performing Endovenous laser therapy with the Console Unit.

Laser Console Case is a hard case used to store the console unit.

Vari-Lase Patient Brochures are sold to our customers, who put them on display for their customers.

HK Surgical Klein Pump II is an infiltration pump designed for delivering local anesthesia using three rollers to create pumping action in a silicone section of tubing. The Klein Pump is intended for repeated use. Federal law restricts this device to sale by or on the order of a physician. Please see the HK Surgical Klein Pump *Instruction Manual* for a complete listing of the indications, contraindications, warnings and precautions.

Klein Infiltration Kits consist of sterilized, one time use tubing, for use with the Klein Infiltration Pump.

InnerChange Catheter combines a micro-introducer kit for obtaining vascular access with a hydrophilically coated diagnostic catheter. The INNERCHANGE catheter is designed to be used for delivering radiopaque media to selected sites in the vascular system in conjunction with routine diagnostic procedures. The INNERCHANGE micro-introducer catheter is compatible with ≤0.038"/ .965mm guidewires. Each INNERCHANGE micro-introducer catheter consists of the following components: 21G percutaneous entry needle, 0.018" guidewire, dilator, and catheter with selected tip shape and attached stopcock. This is supplied sterile as a disposable, single use product. Federal law restricts this device to sale by or on the order of a physician. Please see the INNERCHANGE Catheter *Instructions for Use* for a complete listing of the indications, contraindications, warnings and precautions.

Vari-Lase Compression Stockings provide graduated medical compression combined with elegance for patients. They provide PostOp compression (Class II, 30-40mmHg), are thigh high and feature an open toe.

Gopher Support Catheters are single lumen catheters designed for use in the arterial vasculature. The catheters provide support for guidewires during interventional procedures and allow for the exchange of one disally located guidewire for another while maintaining access to distal vasculature. The 3F GOPHER catheter is designed to assist in the passage of the catheter through lesions by rotating the catheter in a clockwise direction. The 2F model (5600) has a tapered distal tip, and the 3F model (5610) has a threaded, stainless steel distal tip. The GOPHER catheters each have a radiopaque distal tip and two positioning marks located at 95cm (single mark) and 105cm (double marks) from the distal tip, respectively. The proximal end of the catheters each incorporate a torque device, strain relief and a luer-lock guidewire entry port for flushing. The GOPHER Support Catheters should be used by physicians with adequate training in the use of the device. Federal law restricts this device to sale by or on the order of a physician. Please see the Gopher™ Support Catheters *Instructions for Use* for a complete listing of the indications, contraindications, warnings and precautions.

Guardian™ HV is intended to maintain hemostasis during the use of diagnostic/interventional devices. The device is indicated for maintaining a seal around

diagnostic/interventional devices with outside diameters up to 8.0F (2.67mm or 0.105") during diagnostic/interventional procedures. The Guidewire Introducer is included to facilitate the guidewire's passage through the Guardian™ HV. The device is for single use only, and available only by prescription. The Guardian™ Hemostasis Valve with Guidewire Introducer should be used only by trained physicians. Please see the Guardian™ Hemostasis Valve *Instructions for Use* for a complete listing of the indications, contraindications, warnings and precautions.

Carlucci Catheter Cover provides a water resistant barrier to protect an exposed catheter. It features easy, one-person application and remove. The zipper seal allows for convenient access to the indwelling device. This product is supplied as non-sterile and is for single use only. Federal law restricts this device to sale by or on the order of a physician.

Enclosed are copies of the literature and *Instructions for Use* on the above products. Additional information can be found at SITE, or feel free to contact me with any questions you might have.

DEPARTMENT'S RESPONSE:

Under the Use Tax Act, a tax is imposed upon the privilege of using in the State of Illinois tangible personal property purchased at retail from a retailer. 35 ILCS 105/3. The Use Tax Act imposes a tax of 6.25% on either the selling price or the fair market value, if any, of the tangible personal property, unless otherwise provided by the Act. With respect to prescription and nonprescription medicines, drugs, and medical appliances for human use, the tax is imposed at the rate of 1%. 35 ILCS 105/3-10.

The Retailers' Occupation Tax also imposes a rate of 1% on prescription and nonprescription medicines, drugs and medical appliances for human uses. 35 ILCS 120/2-10. The regulation implementing the 1% rate on foods, drugs, medicines and medical appliances under the Retailers" Occupation Tax provides a guide for determining the applicability of the 1% rate under the Use Tax Act. See 83 Ill. Adm. Code 130.310.

You will note that a medicine or drug is "any pill, powder, potion, salve, or other preparation intended by the manufacturer for human use and which purports on the label to have medicinal qualities." A medical appliance is "an item which is intended by its manufacturer for use in directly substituting for a malfunctioning part of the body." Diagnostic equipment is generally not deemed to be a medical appliance. Some supplies qualify for the low rate, while others do not. Insulin, urine testing materials, syringes, and needles used in treating diabetes in human beings qualify for the low rate.

You can determine the tax status of the products listed in your letter by applying the principles set forth in the Regulation cited above. You may also want to review some of the letter rulings provided on our website regarding this topic, such as ST 07-0160 GIL (April 7, 2003). Please also note that sterile dressings, bandages and gauze qualify for the low rate of tax. Supplies such as non-sterile cotton swabs, tissues and towelettes, however, do not qualify for the low rate of tax.

Further, for your information, the Department has ruled that some catheters can qualify as medical appliances. Catheters that directly substitute for a malfunctioning part of the body, that is, catheters that introduce fluids into the body (for instance, catheters used to pump blood back into the circulatory system in open heart surgery or in hemodialysis, or enteral catheters) or remove fluids

from the body (urological or drainage catheters, or neurological catheters relieving intracranial pressure in hydrocephalics) are subject to the low rate of tax.

Catheters that are used diagnostically (e.g., interventional angioplastic catheters) or as medical tools (e.g., as part of a drug delivery system) do not qualify for the low rate and are fully taxable.

I hope this information is helpful. If you require additional information, please visit our website at www.tax.illinois.gov or contact the Department's Taxpayer Information Division at (217) 782-3336. If you are not under audit and you wish to obtain a binding PLR regarding your factual situation, please submit a request conforming to the requirements of 2 Ill. Adm. Code 1200.110 (b).

Very truly yours,

Debra M. Boggess
Associate Counsel

DMB:msk